

410 IAC 1-4

Rule 4. Universal Precautions

410 IAC 1-4-0.5 Applicability of definitions

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 0.5. The definitions in this rule apply throughout this rule. Additionally, the definitions of any other terms contained in the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) are incorporated by reference. (*Indiana State Department of Health; 410 IAC 1-4-0.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-1 "Blood" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 1. "Blood" means human blood, human blood components, and products made from human blood. (*Indiana State Department of Health; 410 IAC 1-4-1; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-1.1 "Bloodborne pathogens" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 1.1. "Bloodborne pathogens" means pathogenic micro-organisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, HBV and HIV. (*Indiana State Department of Health; 410 IAC 1-4-1.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-1.2 "Contaminated" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 1.2. "Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface. (*Indiana State Department of Health; 410 IAC 1-4-1.2; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-1.3 "Contaminated laundry" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 1.3. "Contaminated laundry" means laundry which has been soiled with blood or other potentially infectious materials or laundry which may contain sharps. (*Indiana State Department of Health; 410 IAC 1-4-1.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-1.4 "Covered individual" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11-4

Sec. 1.4. "Covered individual" means any individual covered by IC 16-41-11-4 whose professional, employment, training, or volunteer activities or duties include any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials. (*Indiana State Department of Health; 410 IAC 1-4-1.4; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-1.5 "Decontamination" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 1.5. "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item which does not require sterilization to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. (*Indiana State Department of Health; 410 IAC 1-4-1.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-2 "Department" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 2. "Department" means the Indiana state department of health. (*Indiana State Department of Health; 410 IAC 1-4-2; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-2.1 "Employee" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11; IC 22-8-1.1-1

Sec. 2.1. "Employee" has the meaning set forth in IC 22-8-1.1-1. (*Indiana State Department of Health; 410 IAC 1-4-2.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-3 "Employer" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11; IC 22-8-1.1-1

Sec. 3. "Employer" has the meaning set forth in IC 22-8-1.1-1. (*Indiana State Department of Health; 410 IAC 1-4-3; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-3.1 "ERP" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 3.1. "ERP" means expert review panel, as defined in section 8.1 of this rule. (*Indiana State Department of Health; 410 IAC 1-4-3.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-4 "Facility" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4. "Facility" means a building or location where an individual can be reasonably anticipated in the course of performing his or her professional, employment, training, or volunteer activities or duties to have skin, eye, mucous membrane, or parenteral contact with potentially infectious materials. (*Indiana State Department of Health; 410 IAC 1-4-4; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-4.1 "HBeAg" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.1. "HBeAg" means the presence of hepatitis B e antigen in human blood as an indicator of high infectivity for hepatitis B virus. (*Indiana State Department of Health; 410 IAC 1-4-4.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-4.2 "HBsAg" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.2. "HBsAg" means the presence of hepatitis B surface antigens in human blood as an indicator of infectivity for hepatitis B virus. (*Indiana State Department of Health; 410 IAC 1-4-4.2; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-4.3 "HBV" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.3. "HBV" means hepatitis B virus. (*Indiana State Department of Health; 410 IAC 1-4-4.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-4.4 "Health care worker" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.4. "Health care worker" means any covered individual providing health care for or to a patient during the patient's care or treatment and whose professional, employment, volunteer, or student training duties or activities can be reasonably anticipated to result in skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials. (*Indiana State Department of Health; 410 IAC 1-4-4.4; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-4.5 "HIV" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.5. "HIV" means human immunodeficiency virus. *(Indiana State Department of Health; 410 IAC 1-4-4.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.6 "Other potentially infectious materials" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 4.6. "Other potentially infectious materials" means the following:

(1) Human body fluids as follows:

(A) Semen.

(B) Vaginal secretions.

(C) Cerebrospinal fluid.

(D) Synovial fluid.

(E) Pleural fluid.

(F) Pericardial fluid.

(G) Peritoneal fluid.

(H) Amniotic fluid.

(I) Saliva in dental procedures.

(J) Any body fluid that is visibly contaminated with blood.

(K) All body fluids where it is difficult or impossible to differentiate between body fluids.

(2) Any unfixed tissue or organ, other than intact skin, from a human, living or dead.

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(Indiana State Department of Health; 410 IAC 1-4-4.6; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-4.7 "Parenteral" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 4.7. "Parenteral" means piercing the mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, or abrasions. *(Indiana State Department of Health; 410 IAC 1-4-4.7; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.8 "Sterilize" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 4.8. "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. *(Indiana State Department of Health; 410 IAC 1-4-4.8; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-5 "Universal precautions" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 5. "Universal precautions" means an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. (*Indiana State Department of Health; 410 IAC 1-4-5; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-6 Facility operator responsibilities

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 6. (a) An individual or entity that is a facility operator shall comply with the following:

(1) Inform all health care workers and covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility, that it is strongly recommended by the department that all persons who have reason to believe they are at risk of HIV infection should know their HIV status.

(2) Inform all health care workers that it is strongly recommended by the department that all those:

(A) who perform procedures during which there is a recognized risk of percutaneous injury to the health care worker, and, if such injury occurs, the health care worker's blood may contact the patient's body cavity, subcutaneous tissue, or mucous membranes; and

(B) who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.

(3) Ensure that the training described in the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) is provided to all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility.

(4) Ensure that a record is maintained, as required under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) of an individual's participation in the training that is provided. The record shall be made available to the department for inspection upon request.

(5) Ensure that each covered individual whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility, is provided appropriate equipment and expendables needed to implement the precautions required under section 8 of this rule and under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(6) Require all health care workers whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility to provide evidence of compliance with the continuing universal precautions education requirements contained in section 7.1 of this rule.

(b) The operator of a facility, if providing services to patients or the public in which there is a risk of skin, eye, mucous membrane, or parenteral contact to human blood or other potentially infectious materials, shall display, or make available to the public, a description of compliance with the requirements contained in subsection (a)(6).

(c) The operator of a facility, if providing services to patients or the public in which there is a risk of skin, eye, mucous membrane, or parenteral contact to human blood or other potentially infectious materials, shall display, or make available to the public, written materials prepared or approved by the department explaining universal precautions and patients' rights under this rule. These materials shall include information on how to report violations of universal precautions and shall include information regarding the department's duties to investigate. (*Indiana State Department of Health; 410 IAC 1-4-6; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-7 Facility operator policies

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 7. A facility operator shall develop a written policy in compliance with this rule and the requirements of the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030), that:

- (1) requires the use of universal precautions by a covered individual when performing those professional, employment, training, or volunteer activities or duties that include any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials;
- (2) provides sanctions, including discipline and dismissal, if warranted, for failure to use universal precautions; and
- (3) proscribes the facility operator, or any covered individual acting at or on behalf of the facility, from retaliating against any person, including any professional, employee, trainee, volunteer, or patient, for filing a complaint with the department in good faith under this rule.

(Indiana State Department of Health; 410 IAC 1-4-7; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-7.1 Covered individuals' minimum training and certification requirements

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 7.1. All covered individuals shall comply with the following:

- (1) Covered individuals, including health care workers, whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility, must complete the training programs which the facility is required to have employees attend under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

Approved programs under this rule shall be as follows:

(A) A bloodborne pathogen training session provided by a facility or employer under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(B) Unless the department makes a specific determination to the contrary, any continuing professional education program on current universal precautions techniques that has been accepted or accredited by the applicable professional credentialing or health licensing entity.

- (2) Covered individuals who are health care workers shall, either individually or through their employer, upon receipt of a written request by the department, employer, or a patient to whom direct services have been provided, provide evidence of compliance with the requirements of this section.

(Indiana State Department of Health; 410 IAC 1-4-7.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-8 Precautions generally

Authority: IC 16-41-11-9

Affected: IC 16-19; IC 16-41-11

Sec. 8. (a) All covered individuals and health care workers under this rule shall comply with the requirements imposed under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(b) The operator and all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility providing services to patients or other members of the public in which there is a reasonably anticipated risk of skin, eye, mucous membrane, or parenteral contact with human blood or other potentially infectious materials shall also comply with the following requirements:

(1) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(2) Heating procedures capable of sterilization must be used when heat stable, nondisposable equipment is sterilized. Heat labile, reusable equipment requiring sterilization must be sterilized by chemical means. Records must be maintained to document the following:

(A) Duration of sterilization technique.

(B) Mechanisms for determination of effective sterility.

(C) Routine monthly equipment maintenance inspections.

These documents must be made available to the department upon request.

(3) Environmental surfaces and equipment not requiring sterilization which have been contaminated by blood or other potentially infectious materials shall be cleaned then decontaminated. Disinfectant solutions shall:

(A) be a hospital grade, tuberculocidal Environmental Protection Agency (EPA) registered disinfectant; or

(B) be sodium hypochlorite, five-tenths percent (0.5%) concentration, by volume (common household bleach in ten percent (10%) concentration in water); the solution shall be dated and shall not be used if it is more than twenty-four (24) hours old.

(4) If a patient's diagnosis, laboratory analysis, or medical condition requires additional infection control measures or isolation, those specific measures apply in addition to the requirements of this rule and other requirements found at IC 16-19.

(Indiana State Department of Health; 410 IAC 1-4-8; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-8.1 Expert review panel

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 8.1. (a) An HIV infected or HBV infected (and HBeAg positive) health care worker whose practices include digital palpation of a needle tip in a body cavity or the simultaneous presence of the health care worker's finger and needle or other sharp instrument in a poorly visualized or highly confined human anatomic site should either seek the advice of an ERP approved by the department or voluntarily cease these practices.

(b) As used in this rule, "expert review panel" means a group of experts authorized under this rule to provide confidential consultation and advice to HIV and HBV (and HBeAg) infected health care workers as indicated to promote the highest achievable level of safe, professional care. To be deemed authorized, an ERP must be sponsored by an organization which has been approved by the department under subsection (c).

(c) Before any public or private medical, surgical, dental, nursing, or other health care organization may sponsor an authorized ERP under this section, the potential sponsor must be approved by the department as having provided credible assurances that:

(1) the sponsor is capable of establishing specific ERP protocols and procedures that will accomplish the purposes of an ERP under this section; and

(2) it will comply with general protocols to be established and disseminated on request by the department.

(d) The ERP will consist of:

(1) an expert review entity consisting of:

(A) the HIV or HBV infected health care worker's treating physician, either directly or through medical and historical treatment records;

(B) an infectious disease specialist knowledgeable in the epidemiology of HIV and HBV infection;

(C) a health care provider of the same profession as the infected health care provider with expertise in the procedures practiced; and

(D) an infection control expert or epidemiologist; or

(2) any other expert review entity expressly authorized by the department.

(e) An ERP sponsored by an organization approved by the department under subsection (c) will be deemed an authorized ERP.

(f) An ERP shall advise the health care worker whether and how to modify techniques or to cease performing certain procedures. In rendering this advice, the ERP shall consider the past history of the health care worker's technique, and the extent to which, in the context of other indicated procedures with a measurable and unavoidable significant risk to patients, an indicated invasive procedure in the hands of that health care worker does or does not expose patients to the significant risk of HIV or HBV transmission from the health care worker.

(g) The role of the ERP is strictly confidential and advisory to the health care worker.

(h) All proceedings and communications of the ERP shall be confidential. All communications to an ERP shall be privileged communications. Neither the personnel nor any participant in a panel proceeding shall reveal the identity of any health care worker consulting such panel nor any content of communication to the records of or the outcomes of an ERP outside the panel to any person or other entity, other than the health care worker consulting such panel.

(i) No person who participates in an ERP proceeding shall be permitted or required to disclose any information acquired in connection with, or in the course of, the proceeding, any opinion, recommendation, or evaluation of the panel or of any panel member.

(j) The only duty of an ERP is to provide good faith consultation and advice to the HIV or HBV infected health care worker seeking such advice. A health care worker is not, by this rule, relieved of any responsibility, either to himself or herself or to others, for all actions taken or not taken in his or her professional capacity after consulting with an ERP. Neither an ERP nor any member of an ERP is approved by this rule to substitute or assume responsibility for the subsequent actions of the health care worker. No civil or other legal action of any nature shall arise against any member or personnel of an ERP for any good faith act or statement made in the confines of the panel or proceeding thereof.

(k) Neither an ERP nor any member of an ERP shall, by virtue of their consultation and advice, assume any liability of any kind to the health care worker, his or her patients, or any other person. The personnel and members of an ERP shall be immune from any civil action arising from any determination or recommendation made in good faith in the scope of their duties. (*Indiana State Department of Health; 410 IAC 1-4-8.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 759; errata, 17 IR 1009; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-4-9 Complaints

Authority: IC 16-41-11-9

Affected: IC 4-15-2-34; IC 4-15-2-35; IC 16-41-11; IC 25

Sec. 9. A person who believes that this rule has been violated may file a complaint with the department. A complaint must be in writing unless, in the opinion of the department, the violation complained of constitutes an emergency. The department shall reduce an emergency oral complaint to writing. The

department shall maintain the confidentiality of the person who files the complaint. The department shall also comply with the following:

(1) The department shall promptly investigate, or cause to be investigated with available resources, all complaints received alleging violations of this rule.

(2) The department shall not disclose the name or identifying characteristics of the person who files a complaint under this rule:

(A) unless the person consents in writing to the disclosure; or

(B) the investigation results in an administrative or judicial proceeding and disclosure is ordered by the administrative law judge or the court.

Confidential communication of the complaint information to the Indiana department of labor for compliance purposes shall not constitute disclosure for the purposes of this rule.

(3) The department shall give a person who files a complaint under this section the opportunity to withdraw the complaint at any time prior to the issuance of an order under subdivision (2)(B).

(4) A person filing a complaint must make a reasonable attempt to ascertain the correctness of any information to be furnished. Failure to make a reasonable attempt may subject that person to other sanctions available at law.

(5) A determination of a substantiated and unresolved violation of this rule by a health care provider licensed under IC 25 shall be referred by the department to the appropriate licensing board through notification of the attorney general's consumer protection division.

(6) In the investigation of a complaint regarding a violation of this rule, the department shall coordinate the investigation, as appropriate, with the state or federal enforcement agency having jurisdiction over the industry or occupation. All complaints alleging violations of the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) shall be forwarded to the Indiana department of labor.

(Indiana State Department of Health; 410 IAC 1-4-9; filed Oct 6, 1989, 4:20 p.m.: 13 IR 282; filed Nov 22, 1993, 5:00 p.m.: 17 IR 760; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)